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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
CHO, JENNIFER Y	
ART UNIT	**PAPER NUMBER**
1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,914	MARCHAL, ALFRED	
	Examiner	Art Unit	
	Jennifer Y. Cho	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to Applicant's communication filed on 4/12/2007.

Claims 1-17 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

The nature of the invention is directed to the use of compounds of formula I for the preparation of pharmaceutical or cosmetic composition(s) that can be used for the treatment and/or prevention of dermatological lesions, consisting of bruises, vascular disorders on the skin, spider veins, varicoses, blotches on the face, purpura on the face, body or legs, irritation following use of chemical peel, Schamberg's disease or a mixture thereof.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat or prevent dermatological lesions). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that that contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any preventive regimen on its fact.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The burden of enabling one skilled in the art to prevent dermatological lesions would be much greater than that of enabling the treatment of dermatological lesions.

In the instant case, the specification shows how Vitamin K1 oxide is suitable for the treatment of bruises and the reduction of spider veins, but not the prevention. There is no data directed to the treatment and/or prevention of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease.

Thus, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing dermatological lesions consisting of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing these dermatological lesions.

Specifically, it is highly unlikely, and the Office would require experimental evidence to support the contention that the claim specified could actually prevent dermatological lesions by simply administering, by any method, a therapeutically active amount of the claim specified agents. The specification fails to enable one of ordinary

skill in the art to practice the presently claimed method for preventing these dermatological lesions.

"To prevent" actually means to anticipate or counter in advance, to keep from happening etc. (as per Webster's II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compositions can be administered to order to have the "prevention" effect. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with dermatological lesions in general. Since applicants "preventive" assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits.

Applicants have not provided any competent evidence or disclosed test results that are highly predictive for the pharmaceutical use of preventing any dermatological lesion for a human being or other mammal. Hence, one of skill in the art is unable to fully predict possible preventive results from the administration of the claimed compound due to the absence of convincing evidence that said composition has an effect on mammals. No test results are disclosed in the specification that give guidance as to the actual effect of the compound on any mammal for dermatological lesions consisting of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease.

The amount of direction or guidance present and the presence or absence of working examples

The specification fails to provide any examples of the effect of the compound on mammals with dermatological lesions consisting of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease. It fails to provide test results to substantiate the use of a compound of formula I to treat these lesions.

The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include treatment and prevention of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease but the specification does not provide evidence of the effect of any of the claimed compounds on any these dermatological lesions.

The quantity or experimentation needed and the level of skill in the art

It would require undue experimentation of one of ordinary skill in the art to ascertain the effectiveness of the compound in the treatment or prevention of dermatological lesions consisting of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease. Factors such as "sufficient working examples", "the level of skill in the art" and

"predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant claims. The present state of the art is that studies on dermatological lesions are still being conducted. There is a lack of convincing and substantial evidence linking Vitamin K1 oxide to treatment of dermatological lesions consisting of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of treatment or prevention of dermatological lesions consisting of vascular disorders on the skin, blotches on the face, purpura on the face, body or legs, irritation following use of a chemical peel, or Schamberg's disease, the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

In consideration of the Wand factors, it is apparent that undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual

data to the contrary, the amount and level of experimentation needed is undue. Therefore, claims 1 and 3 are rejected under 35 U.S.C. § 112, 1st paragraph.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Elson (WO 97/39746) in view of Elson (U.S. Patent 5,510,391), further in view of Crandall (U.S. Patent 5,945,409).

Elson (WO) teaches a process for the treatment of skin conditions by the application of a Vitamin K1 cream using ethyl alcohol and lecithin granules for cosmetic or pharmaceutical formulation. (see page 6, lines 11-23) Ethyl alcohol, also known as ethanol, is recognized as a solvent and as a penetration enhancer. The lecithin

granules are derived from phospholipids. Creams are well known cosmetic carriers as shown in Elson (WO). (see page 6, lines 1-5)

Elson (WO) is deficient only in the sense that it does not teach the use of the applicant's penetration enhancer ethoxy diglycol, nor does it teach the particular Vitamin K1 derivative, Vitamin K1 oxide. However, the reference teaches a generic Vitamin K1 and discloses ethanol, a well-known penetration enhancer. (see page 6, line 17)

Elson ('391) teaches the equivalency of Vitamin K1 analogs in a cosmetic and/or pharmaceutical formulation for use in treating the skin. (see column 7, lines 18-20) Vitamin K1 oxide would be considered to be a species of the generic teaching of Elson ('391). Additionally Elson ('391) teaches the presence of ethyl alcohol. (see column 3, line 47)

Crandall teaches the equivalency of penetration enhancers, including ethoxy diglycol and ethyl alcohol. (see column 5, line 55). Also, Crandall teaches the equivalency of any liquid, gel, salve, solvent, diluent and fluid ointment base as an effective carrier. (see column 5, lines 35-37) In addition, Crandall discloses the option to have additional vitamins present. (see column 14, lines 38-40)

Regarding claims 4, 5, 8, 14, 15 and 17 which presents limitations as to the particle size of the phospholipids and the percentage of the compound of Formula 1, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results

desired. Note that the prior art provides the same effect desired by applicant, the treatment of the same skin conditions.

The Examiner acknowledges Applicant's argument that the Vitamin K1 oxide compounds of formula I and their use for treating dermatological lesions was not taught or suggested by the combination of Elson (WO) and Elson ('391), or by the Crandall reference. The Examiner also acknowledges Applicant's argument that the combination of Elson (WO) and Elson ('391) fails to teach the use of ethoxy diglycol in a composition containing Vitamin K1 or its analogs.

Applicant's arguments have been considered but have not found to be persuasive. With regard to the teaching of ethoxy diglycol, Crandall teaches the use of ethoxy diglycol (see column 5, line 55). It is permissible for the Examiner to rely on disclosures, which fairly teach embodiments of Applicant's invention. The claims require a multitude of elements and it is reasonable for one of ordinary skill in the art to consider these elements being used together.

Thus, it is the position of the examiner that it is prima facie obvious that Elson ('391) would teach the use of Vitamin K1 oxide and why one would use it. These references are particularly appropriate since they are in the same field of endeavor and are solving the same problem.

With regard to the declaration, the declaration is not found to be persuasive and is not commensurate in scope with the claims for the following reasons:

- A specific formulation is used for the data.
- The ingredients in the Auriderm XO are not in the claim.

- The claims are not limited to Applicant's method of application of twice a day for four days.
- It is not clear based on the data that the product is clearly an improvement over the art with regard to swelling. The prior art shows better results for this evaluation.
- The study does not compare Vitamin K1 oxide with another Vitamin K1 analog, which would be the closest prior art, versus Vitamin K1.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use any penetration enhancer for the ethyl alcohol of Elson (WO) or those recited in Elson ('391), since the enhancers are recognized as being equivalent within the cosmetics technology. (see Crandall, column 5, line 55).

The expected result would be the effective delivery of the cosmetic formulation to the skin to treat the various conditions of the skin, e.g. vascular disorders, spider veins and blotches. Thus, the Examiner finds Applicant's arguments to not be persuasive and the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho JC
Patent Examiner
Art Unit: 1621

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600